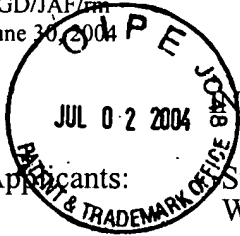


DPW



THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Stephen Randall Holmes-Farley, W. Harry Mandeville, III and George M. Whitesides

Application No.: 10/766,638

Group Art Unit: 1615

Filed: January 28, 2004

Examiner: Not Yet Assigned

Confirmation No.: 3750

Title: Phosphate-Binding Polymers for Oral Administration

CERTIFICATE OF MAILING OR TRANSMISSION	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on:	
<u>6/30/04</u> Date	<u>Rachel Meehan</u> Signature
RACHEL MEEHAN Typed or printed name of person signing certificate	

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or

(First/Second submission after Final Rejection)

☒ under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☐ under 37 CFR 1.97(c) together with either:

☐ a Statement under 37 CFR 1.97(e), as checked below, or

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:

☐ a Statement under 37 CFR 1.97(e), as checked below, and

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.

(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
 - ☒ Copies of the cited references (AQ5, AL6-AQ6, AL7 & AM7) are enclosed.
 - ☒ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
 - ☒ Copies of the cited references are enclosed except those entered in prior applications, U.S. Application Nos. 10/322,904, 09/542,329, 08/929,784, 08/471,747, 08/238,458 and 08/105,591 to which priority under 35 U.S.C. 120 is claimed. The earlier applications contain copies of the cited references.
 - ☒ The listed references (AD4, AE4, AQ5, AL6-AQ6, AL7 & AM7) were cited in the enclosed European Search Report in a counterpart foreign application.
 - ☒ The "concise explanation" requirement (non-English references) for references AM6, AP6 & AL7 under 37 CFR 1.98(a)(3) is satisfied by:
 - ☐ the explanation provided on the attached sheet.
 - ☐ the explanation provided in the Specification.
 - ☒ submission of the enclosed European Search Report.
 - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
 - ☐ the enclosed English language abstract.

☐ Applicant requests that the following non-published pending applications be considered:

Examiner's
Initials

____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

Examiner

Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Jesse A. Fecker
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Concord, MA 01742-9133

Dated: 6-30-04

PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 1932.1004-074		APPLICATION NO. 10/766,638	
INFORMATION DISCLOSURE CITATION IN AN APPLICATION June 28, 2004 (Use several sheets if necessary)		FIRST NAMED INVENTOR Stephen Randall Holmes-Farley		FILING DATE January 28, 2004	
		EXAMINER Not Yet Assigned		CONFIRMATION NO. 3750	
				GROUP 1615	

U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	AA	2,456,428	12-14-1948	Parker
	AB	4,504,640	03-12-1985	Harada, <i>et al.</i>
	AC	4,605,701	08-12-1986	Harada, <i>et al.</i>
	AD	4,071,478	01-31-1978	Shen, <i>et al.</i>
	AE	5,302,531	04-12-1994	Bauer
	AF	4,143,130	03-06-1979	Imondi, <i>et al.</i>
	AG	4,895,621	01-23-1990	Hassler
	AH	3,980,770	09-14-1976	Ingelman, <i>et al.</i>
	AI	4,181,718	01-01-1980	Mason, <i>et al.</i>
	AJ	3,104,205	09-17-1963	Hainer, <i>et al.</i>
	AK	5,053,423	10-01-1991	Liu
	AA2	5,496,545	03-05-1996	Holmes-Farley, <i>et al.</i>
	AB2	5,667,775	09-16-1997	Holmes-Farley, <i>et al.</i>
	AC2	6,083,495	07-04-2000	Holmes-Farley, <i>et al.</i>
	AD2	6,274,713	08-14-2001	Sieving, <i>et al.</i>
	AE2	6,509,013	01-21-2003	Holmes-Farley, <i>et al.</i>
	AF2	5,462,730	10-31-1995	McTaggart, <i>et al.</i>
	AG2	5,428,112	06-27-1995	Ahlers, <i>et al.</i>
	AH2	5,055,197	10-08-1991	Albright, <i>et al.</i>
	AI2	5,430,110	07-04-1995	Ahlers, <i>et al.</i>
	AJ2	5,374,422	12-20-1994	St. Pierre, <i>et al.</i>
	AK2	5,414,068	05-09-1995	Bliem, <i>et al.</i>
	AA3	3,624,209	11-30-1971	Granatek, <i>et al.</i>
	AB3	4,183,918	01-15-1980	Asher, <i>et al.</i>
	AC3	4,205,064	05-27-1980	Wagner, <i>et al.</i>
	AD3	4,247,393	01-27-1981	Wallace

EXAMINER	DATE CONSIDERED
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	AE3	4,631,305	12-23-1986	Guyer, <i>et al.</i>
	AF3	5,108,767	04-28-1992	Mulchandani, <i>et al.</i>
	AG3	5,487,888	01-30-1996	Mandeville, <i>et al.</i>
	AH3	5,702,696	12-30-1997	Mandeville, <i>et al.</i>
	AI3	5,985,938	11-16-1999	Holmes-Farley, <i>et al.</i>
	AJ3	6,177,478 B1	01-23-2001	Holmes-Farley, <i>et al.</i>
	AK3	6,281,252 B1	08-28-2001	Holmes-Farley, <i>et al.</i>
	AA4	6,566,407 B2	05-20-2003	Holmes-Farley, <i>et al.</i>
	AB4	2003 0133902 A1	07-17-2003	Holmes-Farley, <i>et al.</i>
	AC4	6,605,270 B1	08-12-2003	Mandeville, <i>et al.</i>
	AD4	3,308,020	03-07-1967	Tennant, <i>et al.</i>
	AE4	3,332,841	07-25-1967	Ainsworth, <i>et al.</i>

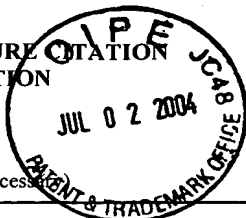
FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO
	AL	GB 2 090 605	07-14-1982	Smith & Nephew	
	AM	WO 94/04596	03-03-1994	E.I. Du Pont de Nemours & Company	
	AN	NL 7603653	10-26-1976	Merck & Company, Inc.	
	AO	EP 0 375 350 A2	06-27-1990	Smith, Kline & French Laboratories Limited	
	AP	EP 0 162 388 A1	11-27-1985	Bristol-Myers Company	
	AQ	FR 2 232 563	01-03-1975	Merck & Co., Inc.	
	AL2	NL 7401543	08-13-1974	Sandoz AG	
	AM2	GB 2 036 048A	11-14-1978	ONO Pharmaceutical Co., Ltd.	
	AN2	WO 94/19379	01-09-1994	British Tech. Group	

EXAMINER

DATE CONSIDERED

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	FIRST NAMED INVENTOR Stephen Randall Holmes-Farley		FILING DATE January 28, 2004	
	EXAMINER Not Yet Assigned		CONFIRMATION NO. 3750	GROUP 1615



FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO	
	AO2	JP 6-321786	11-22-1994	Sekisui Chem. Co. Ltd.		
	AP2	JP 5-244915	09-24-1993	Nitto Boseki Co. Ltd.		
	AQ2	JP 62-132830	06-16-1987	Teijin Ltd.		
	AL3	WO 93/05793	01-04-1993	Corline Systems, AB		
	AM3	JP 4-503962	03-08-1990	UpJohn Company		
	AN3	JP 50-34095	02-09-1975	NEC Corp.		
	AO3	JP 58079022	05-12-1983	Bitamin Kenkyusho: KK		
	AP3	WO 90/02148	03-08-1990	The Upjohn Company		
	AQ3	AU 689797	04-09-1998	Geltex Pharmaceuticals, Inc.		
	AL4	WO 95/05184	02-23-1995	Geltex Pharmaceuticals, Inc.		
	AM4	WO 94/27621	12-08-1994	Geltex, Inc.		
	AN4	AU 480922	02-15-1977	David Henry Solomon, <i>et al.</i>		
	AO4	GB 2,391,730	12-22-1978	Bristol Myers Co.		
	AP4	EP 0 605 757 A1	07-13-1994	Ajinomoto Co., Inc.		
	AQ4	WO 96/21454	07-18-1996	Geltex Pharmaceuticals, Inc.		
	AL5	WO 96/25440	08-22-1996	British Technology Group Limited		
	AM5	GB 2,276,170 A	09-21-1994	British Technology Group Limited		
	AN5	GB 1,573,487	08-20-1980	Bristol Myers Co.		
	AO5	This reference number intentionally left blank.				
*	AP5	GB 2,169,356	07-04-2000	Geltex Pharmaceuticals, Inc.		
-	AQ5	GB 1238597 A ✓	07-07-1971	The Upjohn Company		
	AL6	WO 92/10522 ✓	06-25-1992	Imperial Chemical Industries, PLC		
	AM6	EP 0 379 161 A2 ✓	07-25-1990	Hoechst AG		X
	AN6	GB 929,391 ✓	06-19-1963	Merck & Co., Inc.		
	AO6	WO 94/27620 ✓	12-08-1994	Geltex, Inc.		

* - not found

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FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO	
	AP6	EP 0 534 304 A1 ✓	03-31-1993	Hoechst AG		X
	AQ6	EP 0 449 151 A2 ✓	10-02-1991	Hirayama Chuichi		
	AL7	FR 2 217 010 A ✓	09-06-1974	Sandoz SA		X
	AM7	SU 1808015 A3	04-07-1993	General Genetics Inst. (Abstract Only)		

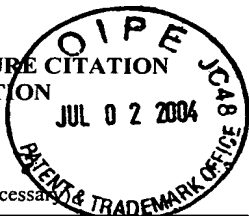
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AR	McGary, T.J., <i>et al.</i> , "Polycation As an Alternative Osmotic Agent and Phosphate Binder in Peritoneal Dialysis," <i>Uremia Investigation</i> , 8(2):79-84, (1984-1985).
AS	Physicians' Desk Reference, Consult 1992 Supplements for Revisions "Phoslo®", Calcium Acetate Tablets.
AT	Physicians' Desk Reference, Consult 1992 Supplementns for Revisions "Amphojel®", suspension Tablets.
AU	Burt <i>et al.</i> , "Ion-Exchange Resins as Potential Phosphate-Binding Agents for Renal Failure Patients: Effect of the Physicochemical Properties of Resins on Phosphate and Bile Salt Binding," <i>Journal of Pharmaceutical Sciences</i> , 76(5):379-383 (1987).
AV	Delmez, James A. <i>et al.</i> , "Hyperphosphatemia: Its Consequences and Treatment in Patients with Chronic Renal Disease," <i>American Journal of Kidney Diseases</i> , XIX(4):303-317 (1992).
AW	Emmett, Michael <i>et al.</i> , "Calcium Acetate Control of Serum Phosphorus in Hemodialysis Patients," <i>American Journal of Kidney Diseases</i> , XVII(5):544-550 (1991).
AX	Ghosh, J.P. <i>et al.</i> , "Preparation and Properties of a New Chelating Resin Containing 2-Nitroso-1-naphthol," <i>Talanta</i> , 28:957-959 (1981).
AY	Mai, Martin L. <i>et al.</i> , "Calcium acetate, an effective phosphorus binder in patients with renal failure," <i>Kidney International</i> , 36:690-695 (1989).
AZ	Munson, Paul L., "Studies on the Role of the Parathyroids in Calcium and Phosphorus Metabolism," <i>Annals New York Academy of Sciences</i> , pp. 776-795 (Jun. 1993).

EXAMINER

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				GROUP 1615	


OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AR2	Salusky, I.B. <i>et al.</i> , "Aluminum Accumulation During Treatment with Aluminum Hydroxide and Dialysis in Children and Young Adults with Chronic Renal Disease," <i>The New England Journal of Medicine</i> , 324(8):537-531 (1991).
AS2	Slatopolsky, Eduardo <i>et al.</i> , "Calcium Carbonate as a Phosphate Binder in Patients with Chronic Renal Failure Undergoing Dialysis," <i>The New England Journal of Medicine</i> , 315(3):157-161 (1986).
AT2	Warshawsky, A., in Ion Exchange and Sorption Processes in Hydrometallurgy Critical Reports on Applied Chemistry, vol. 15, Chapter 4: <i>Chelating ion exchangers</i> , pp.166-225 M. Streat & D. Naden (Eds.), John Wiley & Sons, (1987).
AU2	Winston, Anthony and Kirchner, Darrell, "Hydroxamic Acid Polymers. Effect of Structure of the Selective Chelation of Iron in Water," <i>Macromolecules</i> , 11(3):597-603 (1978).
AV2	Winston, Anthony and McLaughline, Glenn R., "Hydroxamic Acid Polymers. II. Design of a Polymeric Chelating Agent for Iron," <i>Journal of Polymer Science</i> , 14:2155-2165 (1976).
AW2	Petrariu, I., <i>et al.</i> , "Hofmann degradation in quaternary basic ammonium polymers I. Degradation of the linear and crosslined basic benzylic polyelectrolytes in alkaline media," <i>Majer. Plast. (Bucharest)</i> , 9(9):467-472 (1972).
AX2	Shkinev, V.M., <i>et al.</i> , "Anion exchange extraction and enrichment from aqueous solutions by quaternary ammonium reagents," <i>Solvent Extraction and Ion Exchange</i> , 7(3):499-510 (1989).
AY2	Zabutaya, F.I., <i>et al.</i> , "Proton NMR spectroscopic study of the reaction of epichlorahydrin with allyamine," <i>Uzb. Chim. Zh.</i> , 3:23-27 (1984).

* - Not found

EXAMINER	DATE CONSIDERED
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